Brief Commentary

Late Extrusion of an Implantable Pulse Generator of a Spinal Cord Stimulator

Joseph Rabi, MD, and Magdalena Anitescu, MD, PhD

From: University of Chicago Medical Center
Chicago, IL

Address Correspondence:
Joseph Rabi, MD
University of Chicago Medical Center
5841 S Maryland Ave
Chicago, IL
E-mail:
jrabi1@gmail.com

Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 06-09-2015
Revised manuscript received: 09-04-2015
Accepted for publication: 10-26-2015

Free full manuscript:
www.painphysicianjournal.com

The objective of this manuscript was to report a case of a patient with extruded pulse generator 3 years after implantation of a spinal cord stimulator system.

With the increasing incidence of chronic pain, spinal cord stimulation (SCS) is becoming more commonly utilized by pain physicians. SCS is a generally safe intervention with minimal adverse effects; however, there are risks of complications which practitioners should be aware of prior to and after placement of the SCS.

We present a case of a patient with a late complication of extrusion of an implantable pulse generator (IPG) of a SCS that was promptly identified and successfully removed without any complications. A 60-year-old male truck driver with history of failed back syndrome and diabetes underwent a SCS system implanted with excellent relief of his pain. The SCS was implanted with 2 leads with the IPG being sutured 3 cm in depth in the superior gluteal region. Three years after the implantation, he developed pain over the site of the generator and presented to our clinic with extrusion of the non-rechargeable pulse generator from his gluteal region.

The pulse generator was successfully removed with the battery not being infected. This late complication may have been related to his ongoing profession of daily driving with pressure necrosis from prolonged sitting and constant vibration during long rides associated. Structural size and design of the pulse generator may have had an important contribution as well. To our knowledge this complication has not been reported in the literature.

Physicians that place or manage patients with SCSs should be aware of this rare complication and maintain vigilance even after remote implantation of the SCS systems.

Key words: Spinal cord stimulator, complication, extrusion, implantable pulse generator, neuromodulation, failed back syndrome, battery complication

Pain Physician 2016; 19:E671-E674

Despite the instrumental advancements made in spinal cord stimulators (SCSs) in the past 3 decades, complications can occur. The implantable pulse generator (IPG) has evolved over the past 2 decades with significant decrease in both size and weight, and rechargeable capabilities. We report a case of a late complication of an extrusion of an IPG of a SCS system that was promptly identified and successfully removed without any further adverse events.

A 60-year-old man had an L2-L5 laminectomy with fusion for spinal stenosis. Following surgery, performed 5 years prior, his neurological symptoms improved but he continued to have persistent low back pain. When conservative measures failed to provide relief, the patient underwent a SCS trial that was successful in decreasing his pain and subsequently had a non-rechargeable Medtronic SCS system with 2 leads and an IPG (65 mm x 49 mm x 15 mm) placed in his left superior gluteal region. The IPG was sutured into the pocket and the surgical wound was closed in 3 layers both over the lead implants and over the pulse generator. He had a Restore Prime advance generator placed due to his work and traveling as a truck driver and patient's reported difficulties recharging the generator. His SCS

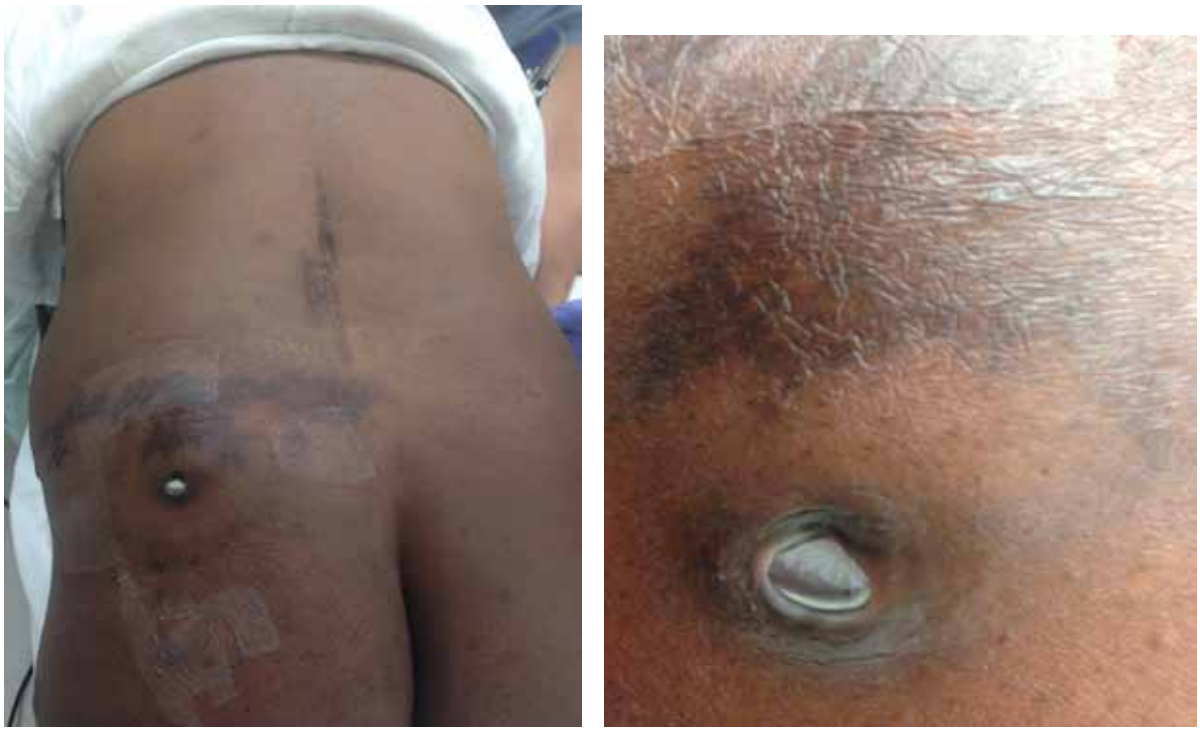

Fig. 1. *Extrusion of the pulse generator.*

had zero complications for 3 years.

At a routine follow-up, he complained of a "metal piece" being exposed from his buttock for one week. He denied fevers, chills, and any weight loss. He reported recent increase work as a truck driver with longer hours. He reported driving 16 hour shifts 4 days per week in the last 3 months. Upon examination, a 1 cm area of generator hardware was extruding from his left superior buttock (Fig. 1). The area was tender without any purulent fluid or erythema around the site. He was given a topical and oral antibiotic. The SCS was removed successfully 5 days later with an expected fibrous band seen around the generator (Fig. 2). An area of 0.2 cm x 1 cm of skin surrounding the area of extrusion was resected and sent for culture, which returned negative. The leads and IPG were sent to pathology for cultures, which returned negative. He completed a 14 day course of cephalexin and was instructed not to drive for 6 weeks.

Most complications occurring in neuromodulation have a technical origin (1). Technical complications include lead migration, lead breakage, battery failure, and skin erosion. The causes of lead migration include extensive scar tissue, too superficial placement of leads, change in body habitus such as sudden weight loss, and increase in mobility of the spine (2-5). Lead breakage is the second most common cause of hardware-related complications with the etiology similar with lead migration (6).

Our case suggests that complications such as hardware extrusion can happen much later after implantation. The only case report that is similar to our case is an extrusion of an IPG in a sacral stimulator but it was due to rapid weight loss after the patient underwent gastric bypass surgery (7). Although IPG extrusion is not routinely present in the neuromodulation literature, there are multiple case reports of pacemaker extrusion in the cardiology literature (8-10).

The extrusion was likely due to pressure necrosis from sitting longer hours. The fibrous pocket that naturally formed and scarred around the generator could have undergone shearing near the site of implantation leading to the extrusion. Another possible cause of the extrusion could be due to larger IPG size causing strain

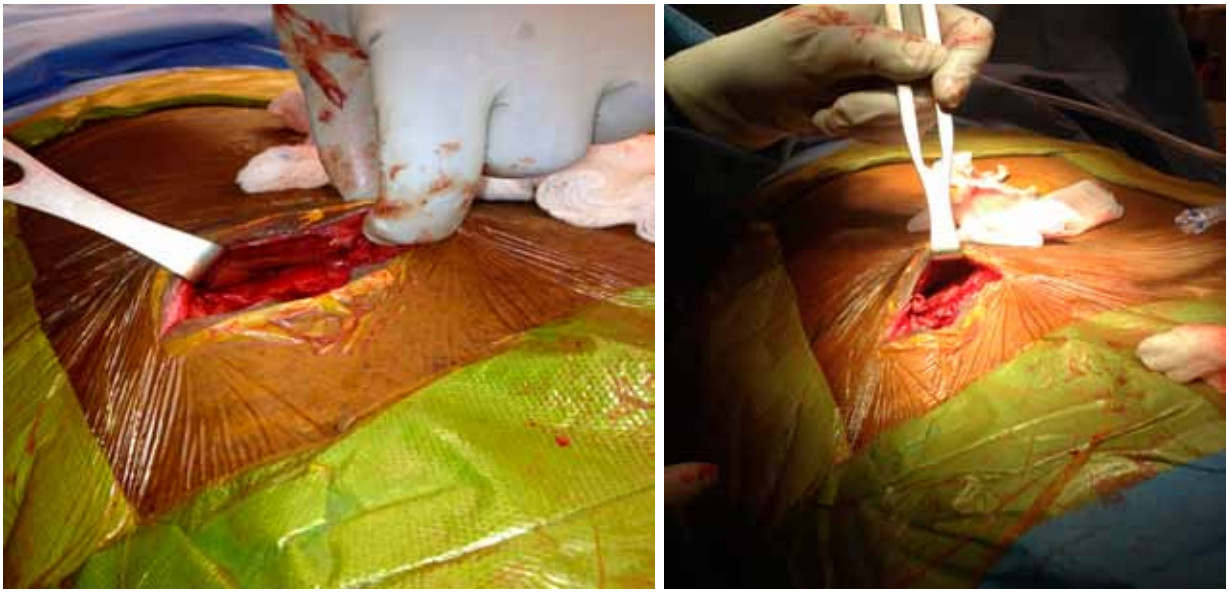

Fig. 2. *Intra-operative evidence of fibrous capsule build-up around the pulse generator.*

on the subcutaneous tissue. The device implanted in our patient had a larger size compared to newer generations of IPGs. We did not consider superficial implantation as a possible factor because the generator was originally implanted about 3 cm deep, securely anchored with non-resorbable sutures, the surgical wound was closed with 3 layers, and the patient had no complications for 3 years after the implantation.

Clinicians should be aware of occupational hazards that could cause excessive pressure on the IPG. Patients with a SCS implanted in the gluteal region should be made aware that prolonged pressure on the IPG can lead to skin necrosis. In order to avoid this complication, clinicians may consider implanting the generator on the abdominal side although this requires longer leads and there may be difficulty in positioning the patient during the procedure. Despite the technological advances in pulse generators being rechargeable, there are patients that would still benefit from non-rechargeable pulse generators, including patients who are not electronic savvy. Rechargeable pulse generators tend to be smaller and weigh less, diminishing the risk of extrusion. There may be a technological opportunity within the neuromodulation community for developing smaller non-rechargeable pulse generators.

References

1. Van Buyten JP. Efficacy of spinal cord stimulation: 10 years of experience in a pain center in Belgium. *European Journal of Pain* 2001; 5:299-307.
2. Anitescu M, Dasilva AN, Frim DM. Intrapleural migration of a spinal catheter in a patient with arachnoiditis and extensive epidural scarring after tethered cord release: A case report and review of literature. *Neuromodulation* 2012; 15:200-203.
3. Kumar K. Avoiding complications from spinal cord stimulation: Practical recommendations from an international panel of expert. *Neuromodulation* 2007; 10:24-33.
4. Takeshima, N, Okuda K, Takatanin J, Hagiwra S, Noguchi T. Trial spinal cord stimulator reimplantation following lead breakage after third birth. *Pain Physician* 2010; 13:523-526.
5. Kumar K, Wilson JR, Taylor RS, Gupta S. Complications of spinal cord stimulation, suggestions to improve outcome, and financial impact. *Journal of Neurosurgery Spine* 2006; 5:191-203.
6. Mekhail, NA, Mathews, M, Nageeb, F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: Indications and complications. *Pain Practice* 2011; 11:148-153.
7. Nold, CJ, Mclennan, MT. Spontaneous extrusion of sacral nerve implant secondary to massive weight loss. *Int Urogynelogy Journal* 2007; 18:105-107.
8. Nichev, Joro, Balabanski, T. A case of total pacemaker extrusion. *European Society of Cardiology* 2009; 11:670.
9. Yuksel, S, Demir, S, Sahin, M. Total extrusion of a normally functioning pacemaker. *Tex Heart Institute Journal* 2012; 39:156-157.
10. Santarpia G, Sarubbi B, D'alto M, Romeo E, Calabro R. Extrusion of the device: A rare complication of the pacemaker implantation. *Journal of Cardiovascular Medicine* 2009; 10:330-332.